

Required Paperwork for Submission to the KUMC Human Subjects Committee

*If more than 1 copy is required, submit as **COLLATED** packets.*

PLEASE DO NOT STAPLE ANY SUBMISSIONS

NOTE: All research personnel must be current on Human Subjects Protection training and Conflict of Interest Disclosure.

I. What paperwork do I need to submit a new study that requires **FULL COMMITTEE REVIEW**?

| Form | Total # of Copies |
|--|------------------------------|
| 1. HSC Application for Full Committee Review | 1 Signed Original & 2 Copies |
| 2. Protocol | 3 Copies |
| 3. Investigator's drug or device brochure (when available) | Only 2 Copies |
| 4. KUMC consent form (If Applicable) | 3 Copies |
| 5. Sponsor's sample consent form (when available) | 3 Copies |
| 6. Grant Application (If Applicable) | 3 Copies |
| 7. Institutional Research Safety Form (IRSC Form) | 1 Signed Original & 1 Copy |

II. What paperwork do I need to submit a new **EXPEDITED** study?

| Form | Total # of Copies |
|---|----------------------------|
| 1. HSC Application for Expedited Review | 1 Signed Original & 1 Copy |
| 2. Protocol | 2 Copies |
| 3. KUMC consent form (If Applicable) | 2 Copies |
| 4. Grant Application (If Applicable) | 2 Copies |
| 5. Institutional Research Safety Form (IRSC Form) | 1 Signed Original & 1 Copy |

III. What paperwork do I need to submit a new **EXEMPT** study?

| Form | Total # of Copies |
|---|----------------------------|
| 1. HSC Application for Exempt Review | 1 Signed Original & 1 Copy |
| 2. Protocol | 2 Copies |
| 3. Grant Application (If Applicable) | 2 Copies |
| 4. Application for HIPAA waiver (for retrospective chart reviews) | 1 Signed Original & 1 Copy |
| 5. Data collection sheet (for retrospective chart reviews) | 2 Copies |

IV. What paperwork do I need to **RE-CERTIFY** my study?

NOTE: Recertification Reminders are sent out 90 days in advance for cancer-related studies and 60 days in advance for other studies

| Form | Total # of Copies |
|--|----------------------------|
| 1. Continuing Review Form | 1 Signed Original & 1 Copy |
| 2. Protocol summary | 2 Copies |
| 3. Copy of the consent form(s) currently being used | 2 Copies |
| 4. Current consent form(s) WITHOUT approval stamp (CLEAN COPY) | 1 Copy |

V. What paperwork is needed to submit a **Response to Provisos**?

When answering provisos, respond by means of a letter outlining the changes and include the following documents, as applicable:

Protocol Revisions (when applicable)

1. A revised protocol, with a new version number and/or version date, accompanied by a letter summarizing the protocol changes.

Consent Form Revisions

1. Revised consent form(s) with changes HIGHLIGHTED (if applicable): 1 copy
2. Revised consent form(s) WITHOUT approval dates (CLEAN) (if applicable): 1 copy

Only ONE copy is needed when submitting Adverse Event (A.E.) Forms, Study Closures, Amendment Request Forms, Updated Drug Brochures, Memos, Reports, or F.Y.I.'s

Revised 8/15/2006

<http://www2.kumc.edu/researchcompliance/human.htm>

HIPAA templates are found at <http://www.kumc.edu/hipaa/research/>